Is primary closure a feasible and acceptable option in the era of t-tube-free common bile duct exploration for choledocholithiasis?

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Introduction
Common bile duct exploration (CBDE) has the advantage of managing cholecystocholedocholithiasis with single-stage procedure. There is still a debate about the benefits and drawbacks after T-tube usage. The aim of this study was to evaluate the value of primary common bile duct (CBD) closure and routine T-tube usage after CBDE.
Patients and methods
A total of 220 patients underwent CBDE by means of choledochotomy for common bile duct stones. Patients were divided into two groups. Group A included 63 patients who were managed with primary closure of the CBD, and group B included 157 patients who were managed using T-tube after assumed CBD clearance. Demographics, preoperative radiology, intraoperative findings, and postoperative complications were collected and analyzed between the two groups.
Results
Among the study patients, 138 patients (63%) underwent laparoscopic common bile duct exploration: 36 patients (57%) in group A and 102 patients (65%) in group B. Wound infection and abdominal collections were significantly more obvious in group B patients ($P<0.004$ and $P<0.003$, respectively). There was no statistically significant difference in bile leakage between the two groups as it was encountered in one patient (1.6%) in group A and in four patients (2.6%) in group B (P=0.065). Residual stones were encountered in 11 patients (5%). Hospital stay was significantly longer in group B patients; the mean hospital stay was 4 days (range=3–35 days) in group B versus 3 days (range=1–13 days) in group A ($P<0.001$).
Conclusion
We encourage primary CBD closure over the use of T-tube, as it provides a more comfortable postoperative course, shorter hospital stay, and is more accepted by patients.

Keywords:
calcular obstructive jaundice, laparoscopic common bile duct exploration, primary closure of common bile duct, t-tube

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Introduction

It is estimated that 10–18% of patients undergoing laparoscopic cholecystectomy have concomitant common bile duct stones (CBDS) [1]. When CBDS are diagnosed, either preoperatively or intraoperatively, several endoscopic and laparoscopic procedures are proposed as management options.

Common bile duct exploration (CBDE) has the advantage of managing CBDS associated with gall bladder stones using single-stage procedure and avoidance of endoscopic retrograde cholangiopancreatography (ERCP) [2,3]. Laparoscopic common bile duct exploration (LCBDE) can be performed using either the transcystic or the choledochotomy approach, depending upon the size and location of the stones and diameter of the common bile duct (CBD) and cystic duct (CD) [2,4].

LCBDE with choledochotomy has the advantage that it can provide an accessible approach to both the CBD and the common hepatic duct, enabling access to more difficult and inaccessible stones. Proponents of systematic biliary drainage might argue that postoperative biliary leaks and collection incidence may be reduced if biliary drainage would have taken place after CBDE. However, there are multiple published reports on the morbidities associated with T-tube drainage [5,6]. Recent systemic reviews showed that primary closure of the CBD alone is superior to T-tube drainage on the basis of the short-term outcome [7,8].

The aim of this study was to evaluate the value of primary CBD closure without external biliary drainage and routine T-tube use after CBDE for choledocholithiasis.

Patients and methods

This was a combined retrospective and prospective study of 220 consecutive patients who underwent CBDE by means of choledochotomy for CBDS from January 2010 to May 2015 in the Gastroenterology Surgical Center, Mansoura University. Patients were divided into two groups. Group A included 63 patients who underwent primary closure of the CBD without any form of external or internal drainage [36 patients (57%) underwent LCBDE]. Group B included 157 patients who were managed using T-tube after assumed CBD clearance [102 patients (65%) underwent LCBDE]. We did not use choledochoscopy in any of the study patients during surgery for confirmation of CBD clearance. Alternatively, we relied upon fluoroscopy-guided intraoperative cholangiography to provide real-time stone extraction and duct clearance. Patients who underwent transcystic stone extraction or transcystic biliary drainage were excluded from the study. In addition, patients who were managed with intraoperative ERCP were also excluded.

CBDS was diagnosed with a combination of clinical examination and thorough history taking together with the supporting laboratory results. Abdominal ultrasound (U/S) and magnetic resonance cholangiopancreatography (MRCP) were performed for all patients. Computed tomography scan was preserved for selected suspicious cases. Liver function tests were carried out for all patients. The diameter of CBD and number and size of stones were measured based on the images of U/S, computed tomography, and MRCP.

In the early period of this study, the CBD was routinely closed over T-tube after CBDE to minimize the risk for bile leak and provide an easy way for confirmation with cholangiography before its removal. Primary closure of the CBD has gained more popularity in the later period of this study. The main determining factor for the choice between the two methods was surgeon preference and experience. The surgical complications were classified according to the Clavien–Dindo classification [9].

The data of demographics, preoperative radiology and laboratory results, intraoperative findings, and postoperative complications were collected and analyzed between the two groups.

Technique of laparoscopic common bile duct exploration

After a patient is placed in the supine position and abdominal insufflation, four trocars are inserted. A 10-mm umbilical trocar or supraumbilical for obese patients, another 10-mm left epigastric port to the left of the falciform ligament, and two 5-mm trocars in the anterior axillary and midclavicular lines were placed. The setting is nearly the same setting we traditionally use for laparoscopic cholecystectomy with the surgeon operating from the left side of the patient.

After the dissection of the gallbladder and division of the cystic artery, the CD and CBD junction is identified and dissected. Further dissection downward is carried out until exposure of the anterior surface of the CBD. At this point, the CD is clipped proximally and a small incision is made in the CD about 2 cm above the junction between the CD and the CBD. The cholangiograsper is introduced through the 5-mm right midclavicular port, or through an extra 5-mm port, with advancement of the tube into the CD and occlusion with the cholangiograsper for obtaining a cholangiogram. The C-arm is positioned to enclose the patient with the operating table, and the dye is injected under fluoroscopic guidance, delineating the biliary anatomy, site, and size if the stone is causing the obstruction. Thereafter, the cholangiogram tube is withdrawn, and the CD is clipped near the CBD.

Longitudinal choledochotomy is performed in the anterior aspect of the CBD using scissors or hook diathermy. After choledochotomy, the stones are pushed out through the opening by manipulating the CBD using blunt forceps and applying saline irrigation. As we do not use choledochoscopy in our center in this series, when stone extraction is more difficult in cases of stones in the left or the right duct or impacted stones at the lower end of the CBD, we traditionally began to use some alternative ERCP instruments. The Dormia basket is introduced and manipulated proximally and distally to grasp the stone. Moreover, some times the ERCP balloon is used in the same way, with the guidewire introduced to facilitate its guidance and direction to withdraw the stone toward the choledochotomy. These steps are usually carried out under fluoroscopic guidance and dye injection for better visualization. At any step during this procedure we obtain an occlusion cholangiogram using Foley's catheter introduced through the 5-mm port and insufflation of the balloon at the choledochotomy for obtaining an occlusion cholangiogram.

After all stones were removed, the clearance of the intrahepatic/extrahepatic bile duct was confirmed with the occlusion cholangiogram. On ensuring that there is free passage of the dye into the duodenum with no evident strictures or stones, the choledochotomy incision was closed over T-tube or primarily. The choice between the two methods was the surgeon's preference and experience. The last step is removal of the gall bladder traditionally.

In group A, primary closure was performed utilizing three or four interrupted vicryl 3/0 sutures, whereas in group B a T-tube of 10–16 Fr was inserted into the choledochotomy incision site after its fashioning and guttering, which was then secured with same type of sutures. A closed suction drain was placed on Morison's pouch in all cases.

Postoperatively, the patients were started on oral fluids on the first postoperative day. The patients were monitored with regard to vital signs, drain, and T-tube output, if inserted, on daily basis. Liver function tests were also carried out on daily basis until discharge.

In group A, patients were discharged after 48–72 h, provided abdominal U/S was free of collections or residual stones. In group B, classically, clamping of the T-tube on the third or fourth day was carried out after T-tube cholangiogram and the patient was discharged, provided the abdominal U/S was free of collections or residual stones. T-tube removal was scheduled after 10th to 14th postoperative day as an outpatient procedure after performing a T-tube cholangiogram.

Follow-up

Serum total bilirubin level was evaluated on the first postoperative day (POD1) and the third postoperative day (POD3). Abdominal U/S was performed on a daily basis until discharge. MRCP was performed for patients with sustained elevation of serum bilirubin level or suspicious residual stones to assess the best management strategy. As regards early follow-up, the mean follow-up period was 2 months (range=1–3 months) with abdominal U/S and liver function tests.

Late follow-up extended up to 1 year to compare the two groups as regards recurrent cholangitis due to biliary strictures or recurrent stone formation with abdominal U/S, liver function tests, and MRCP in suspicious cases.

Statistical analysis

Categorical data were expressed as numbers and percentages. Continuous data were expressed as median and range or mean and SD. The χ^2-test was used to compare categorical variables, and the Mann–Whitney test was used to compare continuous variables.

Results

There was no statistically significant difference between the two groups as regards demographic data or clinical presentation. The mean age of the study patients was 55 years (range=18–83 years). There was a slight female predominance among the study patients, with 129 (59%) female and 91 (41%) male patients. Abdominal pain and jaundice were the most common presenting symptoms in the two groups (Table 1). Most of the study patients presented with jaundice; the mean total bilirubin level was 1.8 mg/dl (range=0.4–30 mg/dl). On the basis of preoperative U/S and confirmatory MRCP, all study patients had dilated CBD more than 10 mm with concomitant gall bladder stones and CBDS.

There was no statistically significant difference as regards the intraoperative biliary findings between the two groups. The intraoperative findings correlated with the preoperative radiological investigations in most of the cases. The mean CBD diameter in the study patients was 13.5 mm (range=10–28 mm). A total of 117 patients (53%) had multiple CBDS, 32 patients (50.7%) in group A and 85 patients (54.1%) in group B (Table 2).

Among the study patients, 138 patients (63%) underwent attempted LCBDE: 36 patients (57%) in group A and 102 patients (65%) in group B. However, conversion to open surgery occurred in 12 patients (9%): four patients (6%) in group A and eight patients (5.1%) in group B. The most common cause of conversion was extensive adhesions or failure to achieve complete satisfactory stone clearance in both groups; however, these data were statistically nonsignificant (Table 2).

There was no statistically significant reduction in the serum bilirubin level on the first postoperative day (POD1) with the use of T-tube between the two groups: 1.2 mg/dl (range=0.9–24 mg/dl) and 2 mg/dl (range=0.5–27.2 mg/dl) (P>0.223) in group A and group B, respectively. Moreover, on the third postoperative day (POD3) it was

Table 1 Demographic and preoperative data of the study patients

Variables	Group A (primary closure) (*n*=63)	Group B (T-tube) (*n*=157)	*P* value
Age (years)	52 (22–75)	58 (18–83)	0.03
Sex [*n* (%)]			
Male	21 (33.3)	70 (44.6)	0.127
Female	42 (66.7)	87 (55.4)	
Clinical presentation [*n* (%)]			
Abdominal pain	57 (90.5)	131 (83.4)	0.182
Jaundice	35 (55.6)	93 (59.2)	0.619
Cholangitis	2 (3.2)	5 (3.2)	0.997
Pancreatitis	0 (0)	1 (0.6)	0.528
Medical history [*n* (%)]			
DM	6 (9.5)	22 (14)	0.369
Hypertension	14 (22.2)	32 (20.4)	0.763
Preoperative laboratory			
WBCs (×10^3/ml)	6.5 (4–13)	7.3 (3–36.5)	0.065
Albumin (g/dl)	4 (3–4.8)	4 (2.1–4.9)	0.772
Total bilirubin (mg/dl)	2.1 (0.2–20)	3.1 (0.4–22.3)	0.138
Direct bilirubin (mg/dl)	1.3 (0.4–24.1)	2.2 (0.4–30.1)	0.276
SGPT (IU/ml)	65 (20–351)	51 (20–832)	0.033
SGOT (IU/ml)	57 (20–358)	51 (20–432)	0.24
INR	1 (1–1.2)	1 (1–2)	0.521

DM, diabetes mellitus; INR, international normalized ratio; WBC, white blood cell.

Table 2 Operative data of the study patients

Variables	Group A (primary closure) (*n*=63)	Group B (T-tube) (*n*=157)	*P* value
Procedure [*n* (%)]			
Open	27 (43)	55 (35)	0.145
Laparoscopy	36 (57)	102 (65)	0.213
Failed laparoscopy	4 (6)	8 (5.1)	0.352
Cause of conversion [*n* (%)]			
Unclear anatomy	1 (1.6)	6 (3.9)	0.122
Failed complete stone extraction	3 (4.8)	2 (1.2)	0.283
Duodenal injury	0 (0)	1 (0.6)	0.125
Bleeding	0 (0)	1 (0.6)	0.112
Intraoperative findings			
Liver [*n* (%)]			
Normal	46 (73)	86 (55)	0.221
Fatty	8 (12.6)	40 (25.4)	0.431
Cirrhotic	9 (14.2)	31 (19.7)	0.122
CBD size (mm)	13 (10–24)	14 (10–31)	0.124
CBDS number [*n* (%)]			
Single	31 (49.2)	72 (45.9)	0.251
Multiple	32 (50.7)	85 (54.1)	0.331
Stone size (mm)	11.5 (4–24)	12 (3–30)	0.726

AGPT, serum glutamic-pyruvic transaminase; CBD, common bile duct; CBDS, common bile duct stones; SGOT, serum glutamic oxaloacetic transaminase.

0.9 mg/dl (range=0.9–18 mg/dl) and 1.1 mg/dl (range=0.5–14.5 mg/dl) (P>0.154) in group A and group B, respectively.

Postoperative complications, wound infection and abdominal collections, were significantly more obvious in group B patients (P<0.004 and P<0.003, respectively) (Table 3).

Bile leakage without residual stones was encountered in five patients (2.2%). One patient (1.6%) in group A had bile leakage that stopped conservatively. In group B, bile leakage occurred in four patients (2.6%): in one patient (0.6%) it stopped conservatively without the need for further intervention and another patient (0.6%) needed ERCP and plastic stent placement, whereas the other two patients (1.3%) required

Table 3 Postoperative data of study patients

Variables	Group A (primary closure) (*n*=63)	Group B (T-tube) (*n*=157)	*P* value
(POD1) Total bilirubin level on first day	1.2 (0.9–24)	2 (0.5–27.2)	0.223
(POD3) Total bilirubin level on third day	0.9 (0.9–18)	1.1 (0.5–14.5)	0.154
Drain removal (days)	1 (1–13)	2 (2–35)	0.001
Hospital stay (days)	3 (1–13)	4 (3–35)	0.001
Complications [*n* (%)]	5 (7.9)	19 (12.1)	0.032
Clavien–Dindo classification [*n* (%)] [9]			
I	1 (1.6)	6 (3.8)	0.008
II	0 (0)	1 (0.6)	0.032
IIIA	0 (0)	1 (0.6)	0.032
IIIB	4 (6.3)	11 (7)	0.032
Wound infection [*n* (%)]	0 (0)	5 (3.2)	0.004
Bedside management		4 (2.6)	
Surgical management		1 (0.6)	
Collection [*n* (%)]	0 (0)	2 (1.3)	0.003
Conservative management		1 (0.6)	
U/S-guided tube drainage		1 (0.6)	
Bile leakage without residual stones [*n* (%)]	1 (1.6)	4 (2.6)	0.065
Conservative management	1 (1.6)	1 (0.6)	
ERCP management	0	1 (0.6)	
Surgical management	0	2 (1.3)	
Residual stone management [*n* (%)]	2 (3.2)	9 (5.7)	0.056
ERCP	2 (3.2)	7 (4.5)	
Surgery	0	2 (1.3)	
Mortality [*n* (%)]	0 (0)	0 (0)	

POD1: serum total bilirubin level on the first postoperative day.
POD3: serum total bilirubin level on the third postoperative day.
ERCP, endoscopic retrograde cholangiopancreatography; U/S, ultrasound.

surgical exploration and peritoneal lavage on the fourth and fifth postoperative day with repositioning of the displaced T-tube (Table 3).

Residual stones were encountered in 11 patients (5%). Two patients (3.2%) in group A had residual CBDS and were managed with ERCP sphincterotomy and stone extraction. In group B, residual stones were encountered in nine patients (5.7%): seven cases were managed with ERCP and sphincterotomy with stone extraction, whereas the remaining two cases (1.3%) required surgical exploration for large-sized stones that caused biliary leakage with displaced T-tube (Table 3).

The hospital stay was significantly longer in group B patients with a mean hospital stay of 4 days (range=3–35 days) compared with group A, in which it was 3 days (range=1–13 days) ($P<0.001$). No mortality occurred in any of the study patients (Table 3).

As regards late follow-up (for 1 year), there was no difference between the two groups as regards the occurrence of cholangitis due to recurrent stones or presence of biliary strictures.

Discussion

This is a combined retrospective and prospective study that was conducted in the Gastroenterology Surgical Center, Mansoura University, which is a tertiary referral center dealing with gastrointestinal and hepatobiliary disorders. Among all available technical approaches for LCBDE, the transcystic stone extraction route might be the best approach for patients who fulfill the prerequisites for this technique [10–12]. Transcystic LCBDE, however, suffers from anatomical limitations (too small CD diameter, low cystic–CBD junctions, and obstructive cystic valves) narrow diameter of the CD, or larger stones. Therefore, this technique cannot be adopted as the standard technique for CBDE. Transcystic LCBDE may also be complicated by CD avulsion or perforation of the CBD [13]. Laparoscopic choledochotomy may be preferable in all these situations and has the advantage of allowing a higher rate of complete CBD visualization compared with the transcystic route [13].

We have many published reports concerning laparoscopic and endoscopic management of CBDS [14–20]. In our present study, the main aim was to evaluate whether to close the CBD primarily or over T-tube after choledochotomy and exploration for CBDS. In our study, the main criterion for choosing between primary closure and T-tube use was the surgeon's experience and feasibility of the equipment and situation. Thus, primary CBD closure has gained popularity among our center surgeons in the last 3 years. Almost all primary closures were performed by the senior staff during the latter half of the study period. The main limitation of LCBDE with primary suture is apparently the requirement of advanced laparoscopic skills, instruments, and experience.

Some series reported the use of choledochotomy without any form of biliary drainage in 18–33% of their patients [11,21,22]. In published reports, complication rates after choledochotomy for CBDS range from 4.7 to 17.5% with reinterventions in 0–2.5% of patients, and the incidence of conversion to open surgery range from 1.5 to 17% [11–13,21,23–25]. Previously published reports of LCBDE have shown mortality rates from 0 to 2%; No mortality occurred among our study patients. We relied on conservative management and U/S-guided tube drainage for management of collections.

Whatever the technique used for CBDE and external biliary drainage, either transcystic or through T-tube, it carries a specific morbidity ranging from 0 to 6.3% in series of open CBDE [26–28] and 4 to 16.4% in laparoscopic series [12,13,21,25].

Residual stones after exploration varies greatly between published studies, ranging from 2.6 to 16% [13,21,23–25]. We did not use choledochoscopy in any of the study patients during surgery for confirmation of CBD clearance. Although intraoperative cholangiography allows CBD manipulation under real-time fluoroscopy, the success rate of obtaining complete clearance of the CBD in our study was 95%, as only 11 patients had residual stones and were discovered in the early postoperative period: nine patients in group B and two patients in group A. Residual stones were diagnosed during the T-tube cholangiogram before its clamping or at the time of its removal in group B, whereas in group A residual stones were diagnosed with a combination of laboratory results, U/S, and MRCP. The management of residual stones in our study patients relied mainly on using ERCP in nine cases, whereas two patients required surgery for management. Surgical exploration with repositioning of the T-tube and peritoneal lavage was necessary. Although the presence of T-tube made it easy to diagnose the presence of the residual stones with the T-tube cholangiogram, the pretense of T-tube did not provide an additional route or advantage in the management of residual stones. In our experience, the availability of ERCP in our center and being performed by surgeons made it an easy favorable way for managing residual stones after exploration [16].

These data demonstrate that the presence of T-tube does not provide any additional benefits when it comes to residual stone management. It just provides an alternative bile pathway other than the normal pathway, thus avoiding jaundice and giving time for arranging ERCP. Even when ERCP and stone extraction fails, which did not happen in any of our study patients, it will not be of big value and re-exploration will remain the more logic approach for management. Although it was statistically nonsignificant, it seemed that patients with Primary CBD closure had a lower incidence of biliary leakage. In addition, the presence of T-tube did not prevent biliary leakage.

Bile leakage without residual stones on U/S or MRCP can occur due to many logic factors such as improper clipping or ligation of the CD, improper closure of the choledochotomy, inflamed unhealthy wall of the CBD, or may be leakage from a sectoral duct. Bile leakage without residual stones for more than 2 days was encountered in five (2.2%) patients, with a higher incidence in group B. One patient (0.6%) in group B needed ERCP and plastic stent placement, whereas the other two patients (1.3%) required surgical abdominal exploration and peritoneal lavage on the fourth and fifth postoperative day with repositioning of the displaced T-tube (Table 3). Thus, the presence of T-tube did not add a much anticipated value in managing bile leaks also.

The additional costs, morbidity, and hospital stays associated with the application T-tubes and its removal should be taken into consideration and included in comparative studies. Many published studies highlighted the avoidance benefits of routine T-tube use [29–31] as it may offer a better and more comfortable postoperative outcome and also eliminate the specific morbidity of such foreign body as it may cause CBD obstruction or bile leakage in case of accidental displacement and is associated with an increased risk for parietal infections [26–31], which should eventually lead to an improved overall outcome.

However, proponents of systematic biliary drainage might argue that postoperative biliary leaks and collection incidence might be reduced if biliary drainage, either external or internal, would have taken place after exploration. Actually, it seems to us that, considering the risks and the morbidities that occur from accidentally removed or slipped tubes or drains or displaced, it is a major issue of concern and can be a real troublesome and provide a rough postoperative course [21].

The socioeconomic and intellectual state of the patient is also a main determinant of the duration of hospital stay after many surgical procedures. T-tube drainage further lengthens hospital stays. This certainly applies if the patient remains in the hospital until the T-tube is clamped. Gigot *et al.* [13] reported a median hospital stay of 7.7 days with and 4.7 days without biliary drainage. Martin *et al.* [21] reported a hospital stay of 4 days with and 2 days without T-tubes. In our study, there was a strong statistical significance in terms of hospital stay between the two groups, 3 days (range=1–13 days) in group A and 4 days (range=1–35 days) in the T-tube group. This can be justified as in certain socioeconomic standards, patients with special needs, and elderly patients it would seem unacceptable to be discharged with a functioning T-tube. Moreover, the dehydration and electrolyte disturbances that occur are important issues of concern.

However, some published reports revealed that drains may in fact become harmful if left in place for more than 48 h [32,33]. We used subhepatic drains in all our study patients. Although it did not prevent biliary leakage or collection in those patients who developed that, the use of drains may be for the early detection of any leaks. However, we removed the drains typically after 48–72 h, provided there were no leaks or collection present.

In the present series, we think that two patients who developed biliary leakage that stopped conservatively gained the maximum benefits of drain use, as they needed no radiological intervention. However, two other patients developed collections with the presence of drains in site. Therefore, we cannot judge the value of drain use as we used it routinely in all patients.

Some long-term adverse effects of laparoscopic choledochotomy might still remain unknown as series addressing the long-term risk for stenosis following laparoscopic choledochotomy are lacking. We followed up our patients for 1 year only but after that we are not aware of any stenosis or strictures in the patients of this study and we are working on another clinical trial to evaluate the long-term follow-up after CBDE.

Conclusion

We encourage the primary closure of the CBD as it provides a more comfortable postoperative course, more economic, and more accepted by the patients over the use of T-tube as it is associated with more complications with less anticipated advantages.

Acknowledgements

Ethical approval was obtained from the Ethical Committee of Mansoura Faculty of Medicine. Informed consent was obtained from all patients.

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Conflicts of interest

There are no conflicts of interest.

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